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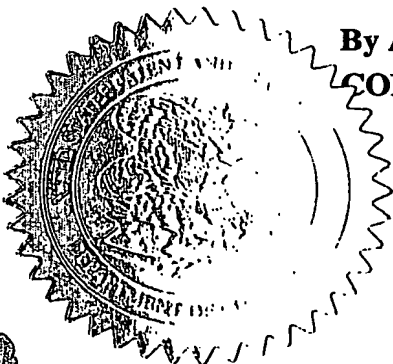
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APPLICATION NUMBER: 60/490,080**FILING DATE: July 25, 2003****PRIORITY
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60/490080

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re: New provisional Patent Application to be filed
Docket No.: ZN 105
Inventor: Wolfgang Schäfer, 73 Drake Lane, Ledgewood, NJ 08752
Title: **METHOD OF PACKAGING AND IDENTIFYING MATERIALS**

Honorable Commissioner for Patents
Alexandria, VA 22313-1450
Mailstop: PATENT APPLICATION

Date: 06/12/01

TRANSMITTAL LETTER FOR NEW PATENT APPLICATION

Sir:

Please find enclosed herewith the following documents relating to the above-identified case:

1. Specification including 11 pages
5 claims
1 page of drawings
2. Declaration and Power of Attorney
3. Assignment and recordation form cover sheet
4. A return postcard for acknowledgement of receipt

The filing fee of \$ 160.-- should be charged to deposit account No. 500465.

Respectfully submitted,

K. Bach

Klaus J. Bach
Reg. No. 26,832

CERTIFICATE OF MAILING - EXPRESS MAIL

Commissioner of Patents and Trademarks:

Enclosed herewith are the following documents:

Application documents for a utility patent entitled:

METHOD OF PACKAGING AND IDENTIFYING MATERIALS

Inventor: Wolfgang Schäfer et al.

Docket No: ZN 105

specification (11 pages spec. with 5 claim, 1 drawing(s))

Assignment and recordation form cover sheet

Declaration and Power of Attorney

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on: 7/25/03

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date

METHOD OF PACKAGING AND IDENTIFYING MATERIALS

BACKGROUND OF THE INVENTION

The invention resides in a method for automatically packaging individual sheet or foil-like materials comprising at least one material layer in a packing unit, which includes a material identification.

5 Sheets or foils of certain materials are used for example in medicine as carrier of pharmacological agents. The materials are provided in the form of thin, lightweight and flexible films. They comprise one or several layers of which at least one includes an effective agent. The material sheets or foils
10 are for example water-soluble. When applied to a human, for example, on the tongue, the materials are dissolved and release the effective pharmaceutical agent.

In order to prevent drying out, the material sheets or foils are generally individually packaged. For packaging, an
15 individual leaf or foil of the material is placed between two packaging webs and the packaging webs are welded together around the leaf or foil so as to form a sealed bag. During placement of an individual material leaf or foil between the packaging webs an air movement or draft is sufficient to change
20 the position of the foil or to move it out of its proper position between the packaging webs. Only after sealing of a package that is after an individual sealed bag has been prepared, it can be determined whether a material foil is actually disposed in the sealed bag.

25 As carrier of pharmaceutical agents, the material foils may be required to carry an identification. Such identifica-

tion may, for example, indicate the type and amount of the agent contained in the material foil.

However, for the application of the identification, the material foil must not be touched. A water-soluble or solvent-containing identification material can therefore not be used since the effective agent concentration in the material foil may be changed by the water or the solvent.

It is the object of the present invention to provide a safe and reliable automatic packaging and identifying method for the packaging of sheets or foils of materials including active agents.

SUMMARY OF THE INVENTION

In a method for the automatic and individual packaging of a sheet or foil consisting of at least one material layer provided with an identification mark, an identification mark of a wax-like material is deposited on a first packaging material web, the material foil or sheet is placed onto the identification mark with a surface thereof which is rougher than the surface of the packaging material web, a second packaging material web is placed onto the first packaging material web and the material foil or sheet, the two packaging material webs are joined around the material foil or sheet to seal the material foil or sheet in a packaging material unit and the packaging material unit is then cooled whereby the identification mark is released from the first packaging material web but remains attached to the material foil or sheet within the packaging unit.

Wax-like materials are of organic nature. At a room temperature of 20°C, they are for example viscous to hard. At higher temperature, they become plastically deformable. At temperature of over 40°C, they may become liquid. With increasing temperature, the viscosity decreases. Wax-like materials are for example naturally occurring animal or plant waxes.

such as bee wax, or artificial waxes such as mixtures of solid paraffins.

For the applications of an identification of a wax-like material, liquid, viscous or solid wax is applied to the heated first packing material web. The wax is applied by spraying from a stationary or movable nozzle with or without the use of a template, by a wax crayon, etc. If the wax is applied in a liquid form to the web its solidification is prevented since the web is heated. If the wax is applied in solid form to the heated packaging material web, the wax is heated in the process to at least a viscous or even a liquid state.

The surface of the packaging material web has only little roughness. The wax adheres therefore to the packaging material web with only little affinity.

In order to attach the material foil to the identification markings applied to the packaging web, the material foil is provided with a rough surface with which it is placed onto the identification markings applied to the packaging web. The two parts adhere to each other with high affinity. For example, a draft cannot change the position of the material foil on the packaging material web as the material foil adheres to the identification markings on the first packaging material web.

In the following method step the second packaging web is placed on top of the material foil and the two packaging webs are welded together by circumferential seal weld. The material foil remains fixed on the identification, which adheres to the first packaging material web.

The packaging unit produced in this way is then cooled so that the wax solidifies. Upon solidification, the wax detaches from the surface of the first packaging material web, but continues to adhere to the surface of the material foil. In this way, the identification is transferred from the packaging web to the material foil.

After completion of the procedure, each packaging unit includes a uniformly positioned material foil provided with an identification.

The method according to the invention consequently provides for an automated packaging and identifying of material foils.

The invention will be described below in greater detail on the basis of the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates the method according to the invention for packaging and identifying material foils.

DESCRIPTION OF A PREFERRED EMBODIMENT

Fig. 1 illustrates a method of packaging and identifying material foils, for example wafers 10 of particular materials. The wafers are water-soluble thin films (foils or sheets) of various thicknesses, which contain a pharmaceutically effective agent. The dimensions of such a wafer are for example 20 x 30 mm.

The method comprises for example five steps (1-5). In a first method step 1, an identification mark 40 is applied to a first lower packaging web 20, for example, by means of a spray apparatus 50.

In a second method step 2, the wafer 10, which is removed for example by means of a suction holder 60 from a magazine 65, is transported to the first packaging web 20 and deposited onto the identification mark 40. During the application of the identification mark 40 and the placement of the wafer 10 onto the identification mark 40, the first packaging web is heated by a heater 70 for example to 40°C.

In the next method step 3, a second, that is, an upper packaging web 30 is placed onto the wafer 10 and the lower packaging web 20.

3
In a fourth method step, the two packaging webs 20 and 30 are joined around the wafer 10 by means of a sealing apparatus 80 by for example four seal joints 25. In this way, a packaging unit 35 consisting of a hermetically closed bag sealed around its four edges and enclosing exactly one wafer 10 is formed.

In the next method step, the four-edge or circumferentially sealed bags 35 are cooled for example at the bottom sides thereof by way of a cooling device 90.

10 The lower packaging web 20 is for example a transparent plastic foil web of for example polyethylene. At least the upper surface 23 of this packaging material web is somewhat rough but generally smooth. It may also be coated with silicon.

15 The lower packaging web 20 is unwound from a drum 21 and extends over a guide roller 22. The packaging material web 20 is aligned and tensioned by radial position-adjustment of the guide roller 22.

20 In the first method step 1, the identification mark 40 is applied to the upper surface 23 of the packaging material web 20, which has been heated. The identification mark consists of a wax-like material, for example of bee wax. It may be transparent or it may be colored.

25 Before the application, the bee wax is heated, for example in the application apparatus 50 by a heater 51 to a temperature of for example 80°C. At this temperature, the bee wax is liquid and has a low viscosity. The application apparatus includes a spray head 5 to which the liquid bee wax is then conducted. The spray head 52 includes for example a template and a nozzle 53 through which the bee wax is ejected onto the packaging web 20. In this way, the image of the template is transferred to the packaging web 20. The bee wax applied as identification mark 40 may have more than one color. The identification mark 40 may comprise for example an alphanumerical, a digital or a color-coded series of markings.

30

The spray head 52 and/or the nozzle 53 may be stationary or they may be movably supported. A movable spray-head and/or a movable nozzle 53 may for example be computer-controlled so that a specific identification mark 40 can be applied to each individual wafer 10. If a computer-controlled spray-head 52 and/or nozzle 53 (like in an inkjet printer) is used, no template is needed.

The application apparatus 50 may include several spray heads 52 and/or nozzles 53. They may all be firmly or movably mounted. The application apparatus may also include a cleaning arrangement for cleaning the nozzle 53.

When the hot bee wax impinges onto the surface 23 of the heated packaging material web 20, the bee wax is cooled. However, since the temperature of the packaging web material 20 is higher than the solidification temperature of the bee wax, the bee wax remains viscous. It adheres to the mostly smooth surface 23 of the packaging material web 20. The identification mark is now readable for example from the underside of the packaging material web 20.

After the application of the identification mark 40, the heated packaging material web 20 is moved forward for the deposition of the wafer 10 onto the heated packaging material web 20 in step 2. The packaging material web 20 may be heated by a heater 70 also during deposition of the wafer 10.

The wafers 10 has at least one surface 11, which has a greater roughness than the surface 23 of the packaging material web 20 has. The wafers 10 are stored in a magazine 65 in such a way that the rough surfaces 11 are facing away from the removal end 66 of the magazine 65.

The wafers 10 are removed from the magazine 65 for example by a suction gripper 60, which is positioned in front of the magazine 65. By establishing a low pressure at the suction surface of the gripper 60 disposed at the removal end 66 of the magazine 65, the first wafer 10 disposed at the removal end 66

of the magazine 65 is engaged and held by the gripper 60. The suction gripper 60 then pivots into a position above the packaging material web 20 and moves axially in the direction toward the packaging material web 20. As soon as the wafer 10 comes into contact in the identification mark 40, the vacuum is switched off. The wafer 10 is then released from the suction gripper 60 and, with its rough surface 11, adheres to the identification mark 40 on the packaging material web 20.

The packaging material web 20 is now moved on for the application, in the next step 3, of the upper packaging material web 30.

The upper packaging material web may consist of the same material as the lower packaging material web 20. It is unwound from a drum 31. It is tensioned and aligned with the lower packaging material web 20 by a guide roller 32. The two packaging material webs 20 and 30 may for example be driven by a common drive. They are then moved with the same cycle frequency and by the same distance.

The cycle frequency may be for example 100 cycles per minute, at which frequency the packaging material webs 20 and 30 are moved, stepwise, with the wafer 10 disposed therebetween, to the sealing apparatus 80 for performing the seal step 4.

The seal apparatus 80 comprises for example upper and lower seal apparatus parts 81 and 86. Both parts include seal heaters 82, 87 and seal weld strips 83 and 88, which are heated by the heaters 82, 87. In Fig. 1, for each part 81, 86 only two sealing strips 83 and 88 are shown for the seal seams extending normal to the transport direction. Of course, additional sealing strips may be provided for the sealing seams extending in the travel direction of the webs. For sealing in the method step 4, the seal apparatus parts 81, 86 are moved toward each other into firm engagement with the packaging material webs 20, 30, which are then welded together. The welding duration is for example 1/160 second. Around the wafer 10 for

example four welding seams 25 are formed so that the wafer 10 is packaged in a packaging unit 35 in the form of a four-edge sealed bag 35. The individual packaging units or bags are interconnected and are moved on together for cooling in step 5.

5 During the cooling step 5, the four-edge circumferentially sealed bags 35 are cooled down to room temperature of 20°C by a cooling apparatus 90 disposed below the sealed bags 35. As the
10 bee wax hardens now fully it becomes detached from the surface 23 of the lower packaging material web 20. But it remains attached to the rougher surface 11 of the wafer 10. As a result, the identification mark 40 is transferred to the wafer 10.

With this method, the wafer 10 or its composition remains unchanged. The wafer 10 retains its active agent concentration and its moisture content.

CLAIMS

What is claimed is:

1. A method for automatic and individual packaging of sheet or foil-like materials consisting of at least one material layer so as to form packaging units whose content is provided with identification marks, said method comprising the steps of:

- providing a first packaging material web;
- heating said first packaging material web;
- applying to said heated first packaging material web an identification mark of a wax-like material;
- depositing a sheet or foil of said material layer with a surface thereof, which has a greater roughness than said first packaging material web, on the identification mark on said first packaging material web;
- placing a second packaging material web over said material sheet or foil and said first packaging material web;
- joining said second packaging material web around said sheet or foil-like material with said first packaging material web so as to form a packaging unit enclosing said material sheet or foil; and
- cooling said packaging unit whereby said identification mark is released from said first packaging material web but remains attached to said material sheet or foil.

2. A method according to claim 1, wherein said first packaging material web is heated also during the application of said identification mark.

3. A method according to claim 1, wherein bee wax is used as material for said identification mark.

4. A method according to claim 1, wherein said material sheet or foil is water-soluble.

5. A method according to claim 1, wherein said material sheet or foil is packaged in a bag having four a sealed edges extending circumferentially around the material sheet or leaf.

ABSTRACT OF THE DISCLOSURE

In a method for the automatic and individual packaging of a sheet or foil consisting of at least one material layer provided with an identification mark, an identification mark of a wax-like material is deposited on a first packaging material web, the material foil or sheet is placed onto the identification mark with a surface thereof which is rougher than the surface of the packaging material web, a second packaging material web is placed onto the first packaging material web and the material foil or sheet, the two packaging material webs are joined around the material foil or sheet to seal the material foil or sheet in a packaging material unit and the packaging material unit is then cooled whereby the identification mark is released from the first packaging material web but remains attached to the material foil or sheet within the packaging unit.

D6031 US

ZN 105

DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION (provisional)
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

As below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name, and I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHOD OF PACKAGING AND IDENTIFYING MATERIALS

the specification of which is attached hereto or was filed on date: under SN:

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with 37 C.F.R. 1.56(a) and 35 U.S.C. 102. I hereby claim foreign priority benefits under 35 U.S.C. 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date (1) before that of the application on which priority is claimed or (2) if no priority claimed, before the filing date of this application:

PRIOR FOREIGN APPLICATION(S)

<u>Number</u>	<u>Country</u>	<u>Day/Month/Year Filed</u>	<u>Priority Claimed</u>
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I hereby claim the benefit under 35 U.S.C. 120/365 of all United States and PCT International applications listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in such prior applications in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose material information as defined in 37 C.F.R. 1.56(a) which occurred between the filing date of the prior applications and the national or PCT international filing date of this application.

PRIOR U.S. APPLICATION OR PCT INTERNATIONAL APPLICATION(S) DESIGNATING THE U.S.

<u>Application Serial No</u>	<u>Day/Month/Year filed</u>	<u>Status: Patented, Pending, Abandoned</u>
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Klaus J. Bach (Reg.-No. 26,832), 4407 Twin Oaks Drive, Murrysville, PA 15668, Tel. 724-327-0664

to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith and with the resulting patent.

1) Inventor's Signature *W. Schäfer* Date 07-25-03
Inventor's Name: Wolfgang Schäfer Citizenship: German

Residence (city): Ledgewood State/Foreign Country: New Jersey
Post Office Address: 73 Drake Lane, Ledgewood, NJ 08752

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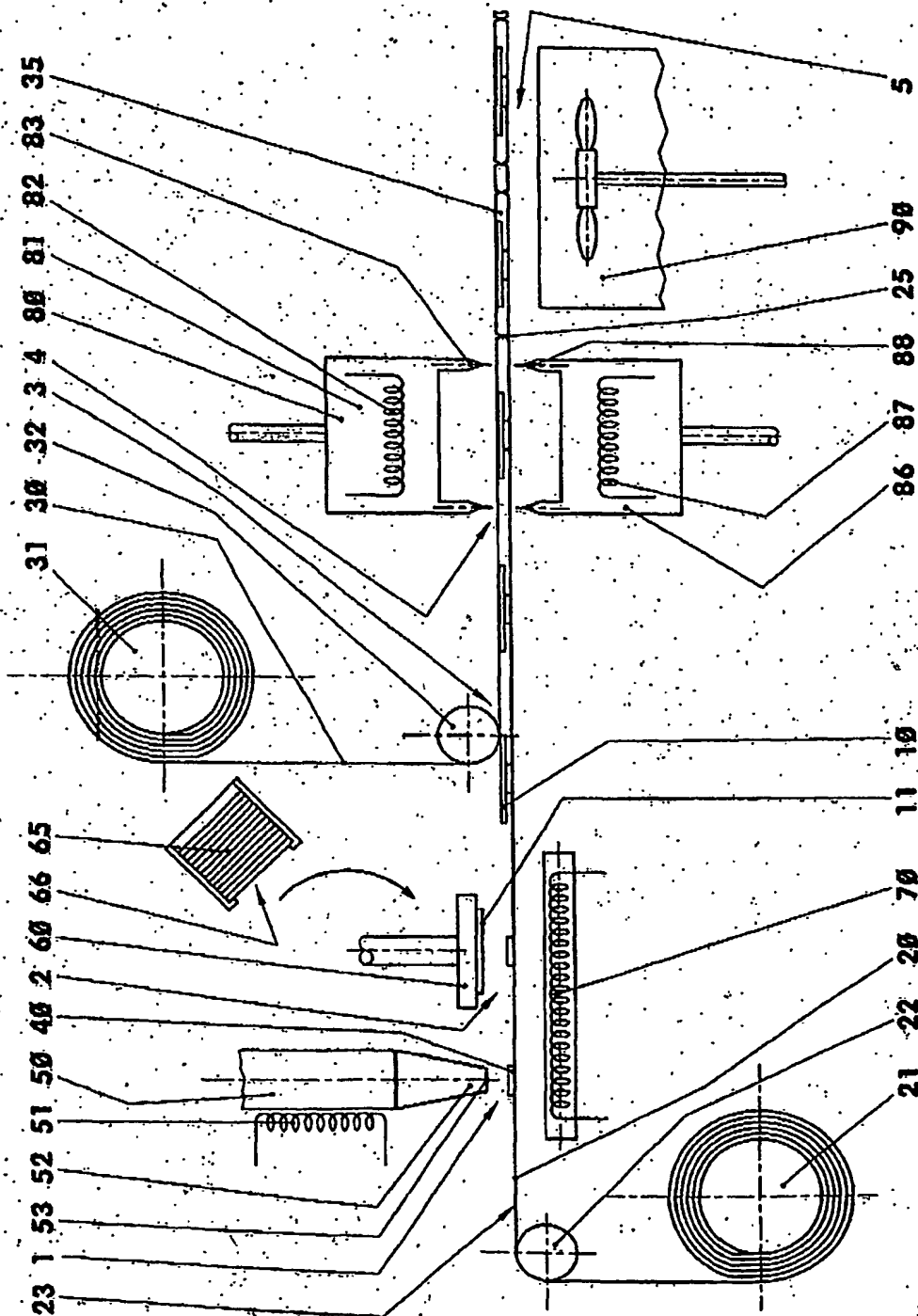


Fig. 1

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